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Efficacy and tolerance of tazarotene cream in lamellar ichthyosis (LI): a dose-finding study

Submission date
24/01/2008

Recruitment status
No longer recruiting

Registration date
14/02/2008

Overall study status
Completed

Last Edited
14/08/2009

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
R00002 CR 2 01 (ORF)

Study information

Scientific Title

Study objectives
The short term efficacy and safety of the tazarotene cream at two different dosages need to be assessed and compared in (lamellar ichthyosis) LI patients, using an intra-individual design (left

/right comparison of tazarotene 0.1% versus tazarotene 0.05% versus vehicle), as a pre-requisite of the phase III pivotal study.

As of 14/08/2009, this record has been updated to include an extended anticipated end date; the initial anticipated end date was 31/12/2008.

Ethics approval required
Old ethics approval format

Ethics approval(s)
France:
1. Ethics committee for protection of biomedical research subjects (Comite de Protection des Personnes), Ile de France II (for all four centres), approved on 11 December 2007

Germany:
Approval obtained from the following ethics committees on 22 November 2007:
1. Ethics committee of the Ludwig-Maximilians University (LMU) Munich, Faculty of Medicine
2. Ethics committee of the Hamburg Clinic
3. Ethics committee of the Westfalen-Lippe Clinic and the Faculty of Medicine, University of Münster (WWU Münster)
4. Ethics Committee of the Georg-August University Goettingen, Faculty of Medicine
5. Berlin State Health and Social Ethics Committee (Landesamt Für Gesundheit Und Soziales, Geschäftsstelle Der Ethik-Kommission Des Landes Berlin)
6. Ethics Committee of the Heinreich-Heine University Düsseldorf, Faculty of Medicine

Primary study design
Interventional

Study design
Period I (4 weeks): Randomised double-blind vehicle-controlled right/left comparison
Period II (8 weeks): Double-blind comparative treatment-free follow-up

Study type(s)
Screening

Health condition(s) or problem(s) studied
Non Erythrodermic Autosomic Recessive Lamellar Ichthyosis (NEARLI)

Interventions
Study treatments:
Tazarotene cream 0.1% or 0.05% and vehicle.

Dose:
Period I (4 weeks): Patients will apply one of the two active test products and the vehicle on the lesions (except on face, scalp, neck and genital areas), on two randomly allocated sides (left side and right side of the body) once daily for 4 weeks (e.g., every evening). This will be associated with the daily application of a standard moisturiser (e.g., in the morning; including face and neck). An adjusted dosage to local tolerance of test products will be performed (no test product application on irritated areas on days when they are observed).

Period II (8 weeks): No application of the test products for 8 weeks; application of the standard moisturiser only.

Mode of administration:
Topical

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Tazarotene

Primary outcome(s)
Assessment of scaling and roughness by the investigator at each of the 10 visits (at screening, baseline, then on days 7, 14, 21, 28 [end of treatment, Period I], 42, 56, 70 and 84 [end of treatment-free follow-up, Period II]).

Key secondary outcome(s)
1. Assessment of the relapse/rebound by the investigator during Period II
2. Time-course severity of each sign (scaling and roughness) during Periods I and II
3. Separate assessment of the overall clinical severity of the lesions on palms and soles for each test side of the body at baseline and end of Period I
4. Assessment of the severity of scaling at baseline and end of Period I
5. Instrumental assessment of scaling on the two forearms using the D-squame technique, at baseline and end of Period I
6. Global local tolerance at end of Period I
7. Overall acceptability by the patients at end of Period I
8. Routine blood laboratory tests (hematology, chemistry) at baseline and at end of Period I
9. Plasma monitoring of tazarotenic acid at baseline and at end of Period I
10. Compliance
11. Physical examination
12. Adverse events

Completion date
20/04/2009

Eligibility

Key inclusion criteria
1. Patients of both sexes of at least 8 years of age
2. Patients with a documented diagnosis of LI based on clinical signs and, if possible, pedigree analysis
3. Patients with both scaling and roughness of moderate to severe intensity on each side of the body
4. Patients or patient's parents/guardians able to understand and follow the study procedures
5. Written informed consent from the patients or parents/guardians
6. Patients or patients' parents/guardians affiliated to a healthcare security system

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key exclusion criteria
1. Patients under 8 years of age
2. Pregnant women, lactating mothers or women of childbearing potential with no reliable medical contraception (combined oral contraceptive, intra-uterine contraceptive device) and unwilling to use condoms, up to 8 weeks after the last test product application
3. Women of childbearing potential with a positive systemic pregnancy test at baseline
4. Patients with congenital ichthyoses other than LI
5. Patients with an erythrodermic component of LI (EARLI)
6. Patients with LI of mild severity on at least one side of the body
7. Patients with lesional superinfection
8. Patients with skin or systemic disease likely to interfere with the study or the evaluation parameters
9. Patients with a known contact allergy to one of the ingredients contained in the test products
10. Patients with sunburn, or excessive pruritus, burning, skin redness or peeling, not fully recovered
11. Patients treated with topicals (e.g., vitamin A analogues, vitamin D analogues) within 14 days prior to baseline
12. Patients treated with keratolytics (e.g., urea, hydroxy-acids) or moisturizers other than the standard moisturizer within 7 days prior to baseline
13. Patients treated with concomitant dermatological medications and cosmetics that have a strong drying effect within 7 days prior to baseline
14. Patients treated with oral retinoids during the preceding 28 days, or with oral vitamin A supplementation (more than 3000 IU per day) during the preceding 7 days of baseline
15. Patients treated with drugs known to be photosensitizers (e.g., thiazides, tetracyclines, quinolones, phenothiazines, sulfonamides, hydrochlorates, chlorpromazine, psoralen, amiodarone, tar) within 2 weeks prior to baseline
16. Patients treated with UV therapy or patients medically exposed to UV within 4 weeks prior to baseline
17. Patients having significant sun exposure due to their occupation
18. Patients with inherent sensitivity to sunlight
19. Patients who participated in a study within the 3 months prior to study entry
20. Patients living with a family member who is currently under test treatment, i.e. Period I of the study (from baseline to day 28)
21. Patients or patients' parents/guardians who are unable to understand and/or to follow the study procedures and patient instructions
22. Patients or patients' parents/guardians who are unwilling to give written informed consent

Date of first enrolment
01/09/2007

Date of final enrolment
20/04/2009

Locations

Countries of recruitment
France

Germany

Study participating centre
4 Rue Marie Curie
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France
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Sponsor information

Organisation
Orfagen (France)

Funder(s)

Funder type
Industry

Funder Name
Orfagen (France)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration